REMARKS

Claims 1, 3-5 and 7-18 are pending. By this Amendment, claims 7-18 are added. Reconsideration in view of the above amendments and following remarks is respectfully requested.

Applicants appreciate the courtesies extended by Examiner Bouchelle and Supervisory Examiner Lucchesi during the interview conducted October 16, 2006. A summary of the interview is incorporated into the remarks below.

Claims 1 and 3 were rejected under 35 U.S.C. § 103(a) over Maruyama et al. (Japanese Patent Application Publication 9-276403) in view of Trudell et al. (U.S. Patent 5,593,393) and Melker (U.S. Patent 5,242,410). The rejection is respectfully traversed.

Claim 1 recites an injection needle comprising a puncture section having a needle point capable of piercing a living body, a proximal end section having outside and inside diameters greater than said puncture section, and a tapered section interconnecting said puncture section and said proximal end section. The proximal end section possesses an outside diameter ranging from 0.35 mm to1 mm and the puncture section possesses an outside diameter ranging from 0.1 mm to 0.5 mm. The length from the puncture section to the tapered section ranges from 0.2 mm to 15 mm. The tapered section possesses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle. The tapered section provides puncture resistance smaller than said puncture section.

MPEP §2143 states: To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either

in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

MPEP § 2141 I. states: Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated: Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. (Underlining emphasis in original.)

The Official Action acknowledges that Maruyama et al. fail to disclose or suggest the claimed 1) proximal end section outside diameter, 2) the puncture section outside diameter, and 3) the tapered section outer profile angle. It is respectfully submitted that Maruyama et al. also fail to disclose or suggest other claimed features, including 4) the claimed length from the puncture section to the tapered section and 5) the tapered section providing smaller puncture resistance than the puncture section. It is further respectfully submitted that Trudell et al. and Melker fail to cure the deficiencies of Maruyama et al.

The Official Action comments that "Trudell teaches a puncturing device having a proximal section... and a puncture section." The Official Action goes on to note

that "the smaller diameter allows for the needle to make as small a puncture as possible for the procedure."

As discussed during the interview, It is respectfully submitted that Trudell et al. do not disclose or suggest a puncturing device. Trudell et al. disclose a lacrimal irrigating cannula 16 that includes a hollow tube 20. The hollow tube 20 has a rounded and smooth forward distal end 8 that allows for easy and safe insertion into the lacrimal puncta 28 of a patient's lacrimal cannalicula 30. The rounded and smooth forward distal end 8 is formed on the end of a distal shaft 12 which is followed by a taper 14 and a larger proximal end 15 of the hollow tube 20.

Trudell et al. disclose in column 1, line 65 through column 2, line 23, nine objects of their invention. Of the nine objects disclosed, none include allowing a needle to make as small a puncture as possible. Contrary to the observation in the Official Action, Trudell et al. also do not disclose or suggest such an object in column 4, lines 5-45.

MPEP § 2143.01 I. states: There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.

It is respectfully submitted that Trudell et al. provides no teaching, suggestion or motivation to modify the needle of Maruyama et al. as Trudell et al. do not disclose or suggest anything regarding the nature of the problem to be solved by Maruyama et al., i.e. reducing the incision width of the blood vessel by the blade surface.

It is also respectfully submitted that Trudell et al. teach away from a combination with Maruyama et al. As described in column 1, lines 1-19, of Trudell et

al., lacrimal cannula, in general, are derivations of intravenous needles and catheters. However, as further discussed in column 1, lines 39 - 60 of Trudell et al., the sharp tip of a needle is not useful for lacrimal punctal as it could cause bleeding and irritation of the lacrimal tissues. Trudell et al. also discuss a two diameter needle cannula for penetration of the skin, but specifically state that extensive modifications would be required for such a needle to be utilized for lacrimal insertion. Trudell et al. further disclose that the modifications of such needles would require a change in use to be used for lacrimal irrigation. The guidance provided by § 2143.01 V. of the MPEP is particularly relevant here. This section states that If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.

As explained in the previous responses, the claimed construction of the injection needle at issue here advantageously reduces the degree of puncture pain experienced by the patient without unacceptably compromising the mechanical strength of the needle and increasing the flow passage resistance when a liquid medication is injected through the needle. This is discussed at, for example, page 11, lines 7-14 of the present application.

As recited in claim 1, the tapered section provides smaller puncture resistance than the puncture section. Referring to pages 21 - 28, and Figure 8 of the instant application, an exemplary injection needle was formed having the dimensions as disclosed on page 21, line 6 through page 22, line 8. As further disclosed on page 22, line 10 through page 23, line 4, an injection needle of a comparative example was also formed.

As shown in Figure 8, the puncture resistance of the tapered section of the injection needle is less than the puncture resistance of the puncture section. However, as also shown in Figure 8, the puncture resistance of the tapered section of the injection needle of the comparative example is higher than the puncture resistance of the puncture region.

During the interview, Examiner Bouchelle's reliance on Trudell et al. was discussed. As noted by Applicants' representative, Applicants do not disagree that Trudell et al. disclose a hollow tubular structure having a first section, a tapered section, and a second section having an outside diameter larger than the outside diameter of the first section. However, Applicants respectfully disagree that Trudell et al. disclose a puncture section having a needle point capable of piercing a living body. Applicants also respectfully disagree that one of ordinary skill in the art would have been motivated to combine Trudell et al. with Maruyama et al. for at least the reasons discussed above.

Examiner Lucchesi noted that if Trudell et al. disclosed the dimensions recited in claim 1, the reference may anticipate claim 1 because the forward distal end 8 of Trudell et al. could be interpreted as a needle point capable of piercing a living body, assuming enough force were applied.

Applicants respectfully submit that Trudell et al. do not disclose the dimensions recited in claim 1. Although Trudell et al. disclose that the dimensions of the cannula may be varied (see, for example, column 4, lines 6-17), as the cannula of Trudell is used for dilating, probing, and irrigating the lacrimal drainage system, even assuming it would have been obvious to vary the dimensions of the cannula in Trudell et al., one of ordinary skill in the art would not have been motivated to select

the dimensions recited in claim 1 because the cannula of Trudell et al. is not intended to pierce a living body. That is, if one of ordinary skill in the art was somehow motivated to vary the dimensions of the cannula described in Trudell et al., one would do so based on the particular manner in which Trudell et al.'s cannula is used. In this regard, it has not been established that it would have been beneficial to construct a cannula for dilating, probing, and irrigating the lacrimal drainage system that possesses the dimensions set forth in Claim 1.

With respect to Melker, the Official Action states that Melker "teaches a needle 1 with a taper from the distal end 5 to the transition point 6 having an angle in the range from about 1.26 degrees to 5.18 degrees." As discussed during the interview, Melker describes a needle of uniform diameter and a tapered dilator that fits over the dilator. Thus, the taper described in Melker applies to the dilator 4. In other words, it is not the **needle** 1 that possesses the disclosed taper, but rather the **dilator** that fits over the needle. Claim 1 does not recite that a dilator used with a needle possesses a tapered section. Accordingly, even assuming it would have been obvious to combine Melker with Maruyama et al. and Trudell et al., which Applicants do not concede, such a combination would not result in an injection needle having all of the claimed features and would thus not present a *prima facie* case of obviousness.

It is also respectfully submitted that Melker does not teach or suggest that the taper on the dilator 4 should also be used on the needle 1. Melker is not concerned with the nature of the problem solved by the claimed injection needle at issue here, i.e., reduced puncture pain. Nor would Melker's disclosure of a uniform diameter needle and a tapered dilator for introduction of a large bore flow sheath have

motivated one of ordinary skill in the art to provide the needle of Maruyama et al. with the claimed taper angle.

As the combination of Maruyama et al., Trudell et al. and Melker fails to include, at least, the claimed length from the puncture section to the tapered section and the tapered section providing smaller puncture resistance than the puncture section, the combination fails to present a *prima facie* case of obviousness.

Moreover, as there is no teaching, suggestion or motivation to combine the references, and as the references actually teach away from such a combination, the rejection fails to present a *prima facie* case of obviousness.

Claim 3 recites additional features of the invention and is allowable for the same reasons discussed above with respect to claim 1 and for the additional features recited therein.

Reconsideration and withdrawal of the rejection of claims 1 and 3 over Maruyama et al. in view of Trudell et al. and Melker are respectfully requested.

Claims 4 and 5 were rejected under 35 U.S.C. § 103(a) over Gross (U.S. Patent 4,781,691) in view of Trudell et al. and Melker. The rejection is respectfully traversed.

The Examiner acknowledges that Gross does not disclose or suggest the claimed 1) proximal end section outside diameter, 2) the puncture section outside diameter, and 3) the tapered section outer profile angle. A study of the disclosure in Gross reveals that Gross also does not disclose or suggest at least, 4) the claimed length from the puncture section to the tapered section and 5) the tapered section providing smaller puncture resistance than the puncture section. It is further

respectfully submitted that Trudell et al. and Melker, alone and in combination, fail to cure the deficiencies of Gross.

Gross discloses that the second tubular portion 16 has an outer diameter of 0.018 to 0.025 inches (approximately 0.46 to 0.635 mm) and the first tubular portion 14 has an outer diameter of 0.025 to 0.050 inches (0.635 to 1.27 mm). This disclosure in Gross would appear to make the Official Action's reliance on Trudell et al. unnecessary. However, Applicants respectfully submit that the combination of Trudell et al. with Gross is improper for the same reasons discussed above with respect to the combination of Maruyama et al. and Trudell et al. There is no motivation to combine the lacrimal cannula of Trudell et al. with the needle of Gross, and the references actually teach away from their combination.

Gross does not disclose or suggest that the intermediate portion 18 has a smaller puncture resistance than the second tubular portion 16. In fact, Gross discloses that the intermediate section 18 does not puncture either the ligamentum flavum L or the dura mater D.

Gross describes in column 3, line 66 through column 4, line 1 that the minimum length of the second tubular portion 16 is in a range which accommodates the thickness of the ligamentum flavum L and the dura mater D. Gross further discloses in column 4, lines 56-60 that that the relatively small second tubular portion 16 makes a sufficiently small opening in the dura mater D such that the opening will close and prevent leakage of the cerebrospinal fluid CSF. See also Gross's discussion in column 1, lines 53-56 of the need for a small needle for use in a spinal anesthesia procedure to prevent the leakage of cerebrospinal fluid. Based on these disclosures, one of ordinary skill in the art would not have been motivated to

puncture the ligamentum flavum L or the dura mater D with the intermediate portion 18 of the needle. Nor would one of ordinary skill in the art expect the advantages of the claimed needle, including reduced pain associated with puncture.

As Gross does not disclose or suggest that the intermediate section 18 punctures the ligamentum flavum L or the dura mater D, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to provide the intermediate section 18 with a taper angle as disclosed by Melker for the reasons stated in the Official Action.

The combination of Gross, Trudell et al. and Melker fails to include the claimed length from the puncture section to the tapered section and fails to disclose or suggest a tapered section that provides puncture resistance smaller than the puncture section. There is also no motivation or suggestion to combine the references, and the references actually teach away from such combination. The combination thus fails to present a *prima facie* case of obviousness.

Claim 5 recites additional features of the invention and is allowable for the same reasons discussed above with respect to claim 4 and for the additional features recited therein.

Reconsideration and withdrawal of the rejection of claims 4 and 5 over Gross in view of Trudell et al. and Melker are respectfully requested.

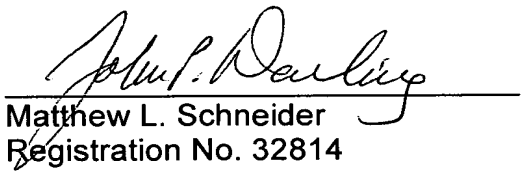
As discussed during the interview, new claims 7-18 recite additional features associated with the claimed needle and instrument, and are allowable at least by virtue of their dependence from allowable claims 1 and 4.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful

in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: October 19, 2006 By: 

Matthew L. Schneider
Registration No. 32814

John P. Darling
Registration No. 44482

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620